

Remarks/Arguments

Claims 1-10 and 63, 65 and 66 examined and rejected. By this Amendment, claims 1-3, 63 and 66 are amended. Claims 11-31, 42-53, 56-58, 61, 62, 64 and 67-69 were canceled in a previous response. Claims 32-41, 54, 55, 59 and 60 were previously withdrawn in response to a Restriction Requirement. Accordingly, claims 1-10 and 63, 65 and 66 remain pending in the application.

The amendments to the claims are fully supported by the specification and the figures, in particular paragraphs [0038] and [0039]. Accordingly, no new matter has been added. Reconsideration and allowance of the claims as amended is respectfully requested in view of the comments made below.

I. §112 Rejections

Claims 1, 2, 63, 65 and 66 are rejected under 35 U.S.C. §112, first paragraph, as the Examiner contends that "without augmentation" is not supported in the specification. Claims 1 and 63 have been amended to recited that the seamless member is itself sufficient rigid to penetrate skin. This is supported in the specification in at least paragraphs [0038] and [0039]. For example, the "[u]nitary member is preferably constructed of a gage, full hard, stainless steel material to ensure that lancet will have the necessary rigidity to function properly." As noted in paragraph [0037], the function of the lancet is to be fired into the skin of a patient in order to acquire a blood sample. Applicant submits that this rejection is overcome.

Claim 5-10 are rejected under 35 U.S.C. §112, second paragraph. Claim 5 is rejected because, as stated by the Examiner, there is no three dimensional object being claimed in claim 5. Applicants traverse this objection. Claim 5 recites that the unitary member includes a longitudinal axis, a lateral axis, a vertical axis, a horizontal plane and a vertical plane. The unitary member is clearly a three dimensional object, described as an elongated, seamless, cylindrical tube in paragraph [0040]. As clearly described in the Specification in at least paragraphs [0042]-[0044] and [0057] and

shown in Fig. 1(a), the longitudinal axis X and lateral axis Y define a horizontal plane XY. Vertical axis Z together with longitudinal axis X define the vertical plane XZ. To overcome the rejections, claim 5 is canceled, the dependency of claim 6 is corrected, and claim 8 is amended to define the horizontal plane. Applicant submits the rejection is overcome. Applicant also submits that the claim and specification objections are overcome.

II. Anticipation Rejection

Claims 1, 2, 63, 65 and 66 have been newly rejected under 35 USC §102(b) as allegedly being anticipated by Ross et al. (US 6,702,790). See Office Action, p. 6.

Independent claim 1 (and claim 2 dependent thereon) recites in part a lancet device comprising a lancet including a seamless member which is hollowed along a portion of its length, the seamless member having a first end and a second end, wherein the first end of the seamless member is shaped to include first and second sharpened tips, the first and second sharpened tips spaced directly opposite each other on the seamless member and extending parallel to a longitudinal axis of the seamless member, wherein the seamless member is itself sufficiently rigid to penetrate skin, and a lancet holder arranged and configured on the second end of the lancet to move the lancet a penetration distance to penetrate the skin of a patient with the first and second sharpened tips, wherein the penetration distance is less than a length of the sharpened tips.

Support for the first and second sharpened tips spaced directly opposite each other on the seamless member and extending parallel to a longitudinal axis of the seamless member can be found in Figs. 1a-d and in paragraphs [0043]-[0045]. Support for a partially hollow lancet is found in paragraph [0041]. Support for the penetration distance is less than a length of the sharpened tips is found in paragraph [0048].

Ross discloses a needle having two prongs spaced less than 180 degrees apart. See Figs. 10-12 and 15 and column 6, lines 18-23. Ross does not disclose first and second sharpened tips spaced directly opposite each other on the seamless member and extending parallel to a longitudinal axis of the seamless member. Ross also discloses medical needles for penetrating bodily cavities from which fluid flows from the cavity through the needle, such as intravenous needles and catheters. (Col. 1) Clearly, the needle would need to penetrate beyond the length of the tips to create a seal with the skin so that fluid flows through the needle and not out through the needle onto the skin. In addition, the needle of Ross is entirely hollow to transport liquid rather than partially hollow as claimed. For at least these reasons, Ross does not anticipate claims 1 and 2.

Independent claim 63 (and claims 65 and 66 dependent thereon) recites in part a partially hollow lancet having an outer wall defining a first ground surface and a second ground surface, the first and second ground surfaces each forming a gullet that extends approximately 180 degrees about a longitudinal axis of the lancet forming at an intersection a first tip and a second tip at the first end, and wherein the outerwall is itself sufficiently rigid to draw fluid from a patient; and a lancet holder arranged and configured on the second end of the lancet to move the lancet to a penetration depth to penetrate the skin of a patient with the first and second tips, the penetration depth being less than a length of the gullet measured along the longitudinal axis.

Support for first and second ground surfaces each extending approximately 180 degrees about a longitudinal axis of the lancet can be found in paragraph [0044]. Support for a partially hollow lancet is found in paragraph [0041]. Support for a lancet holder arranged and configured on the second end of the lancet to move the lancet to a penetration depth to penetrate the skin of a patient with the first and second tips, the

penetration depth being less than a length of the gullet measured along the longitudinal axis is found in paragraph [0048].

Ross discloses a needle having two prongs spaced less than 180 degrees apart. See Figs. 10-12 and 15 and column 6, lines 18-23. Ross does not disclose first and second ground surfaces each extending approximately 180 degrees about a longitudinal axis of the lancet and forming at an intersection a first tip and a second tip at the first end. Ross also does not disclose a lancet holder configured to move the lancet to a penetration depth to penetrate the skin of a patient with the first and second tips, the penetration depth being less than a length of the gullet measured along the longitudinal axis, for the reasons discussed above. In addition, the needle of Ross is entirely hollow to transport liquid rather than partially hollow as claimed. For at least these reasons, Ross does not anticipate claims 63, 65 and 66.

III. Obviousness Rejections

Claims 1-10 and 63, 65 and 66 are rejected as allegedly being obvious under 35 USC §103(a) over Ayres (US 3,906,932), in view of Humphrey (US 5, 607, 401). See Office Action, p. 9.

Claim 1 (and claim 2 by its dependency) recites a lancet device comprising (a) a lancet including a seamless member which is hollowed along a portion of its length, the seamless member having a first end and a second end, wherein the first end of the seamless member is shaped to include first and second sharpened tips, the first and second sharpened tips spaced directly opposite each other on the seamless member and extending parallel to a longitudinal axis of the seamless member, and wherein the seamless member is itself sufficiently rigid to penetrate skin; and (b) a lancet holder arranged and configured on the second end of the lancet to move the lancet a penetration distance to penetrate the skin of a patient with the first and second

sharpened tips, wherein the penetration distance is less than a length of the sharpened tips.

Claim 3 (and claims 4-10 by their dependency) recites a lancet device comprising a lancet including a unitary stainless steel member which is hollowed along a portion of its length, the unitary stainless steel member including a first end and a second end, wherein the first end of the unitary member includes first and second ground surfaces which at least partially define first and second sharpened tips and each define a gullet between the sharpened tips; and a lancet holder arranged and configured on the second end of the lancet to move the lancet a penetration depth to penetrate the skin of a patient with the first and second sharpened tips, the penetration depth being less than a length of the gullet. Support for the amendments is found in paragraphs [0041] and [0048].

Claim 63 (and claims 65 and 66 by their dependency) recites a lancet including a partially hollow member having an outer wall, a first end, a second end and a length therebetween, wherein the outer wall defines a first ground surface and a second ground surface, the first and second ground surfaces each forming a gullet that extends approximately 180 degrees about a longitudinal axis of the lancet forming at an intersection a first tip and a second tip at the first end, and wherein the outerwall is itself sufficiently rigid to draw fluid from a patient; and a lancet holder arranged and configured on the second end of the lancet to move the lancet to a penetration depth to penetrate the skin of a patient with the first and second tips, the penetration depth being less than a length of the gullet measured along the longitudinal axis.

The Examiner has failed to make a *prima facie* case of obviousness. As noted by the Examiner on page 10 of the Office Action, Ayres fails to disclose both ends of the needle having the same needle point design. Humphrey also fails to disclose both ends of the needle having the same needle point design. One skilled in the art would not look to Humphrey to modify Ayres as Ayres explicitly teaches against the use of the desing

in Fig. 12 of Humphrey. Furthermore, Ayres only discussed the end of the needle penetrating a stopper. There is no motivation for one skilled in the art to look to a reference disclosing skin penetrating needles to modify Ayres, which only discussed a needle penetrating a stopper. Therefore, the combination of Ayres and Humphrey does not teach, suggest or render obvious the limitation put forth by the Examiner (as it is not claimed) that both ends of the needle having the same needle point design.

Ayres does not teach or suggest a lancet including a seamless member which is hollowed along a portion of its length. The needle in Ayres was designed to penetrate the rubber stopper of a Vacutainer so that the hollow needle can transport blood from the wound to the Vacutainer. Humphrey also discloses in Fig. 12 a hollow needle. (Col. 5, lines 4-5). "Figs. 10 through 12 show perspective views of various tip geometries for the polymeric hypodermic needle (50)." Col. 10, lines 47-48). The Humphrey needle is hollow to transport fluid. The Examiner has failed to provide a reference that teaches or suggests a partially hollow lancet. The Examiner has also failed to provide why one skilled in the art of using a lancet that pricks the skin and is then withdrawn from the wound so that the blood is exposed for testing purposes, as noted in paragraph [0048], would look to two references that teach hollow needles for transporting fluid to design a tip. Therefore, the combination of Ayres and Humphrey does not teach, suggest or render obvious a partially hollow seamless member as recited in the claims.

Ayres also fails to disclose a penetration distance to penetrate the skin of a patient with the first and second sharpened tips, wherein the penetration distance is less than a length of the sharpened tips. As noted above, Ayres does not discuss penetrating skin. In addition, as clearly shown in Fig. 5, "an elevational view . . . showing the needle of the present invention penetrating a stopper of an evacuated tube," the tips of the needle penetrate the entire stopper and come out the other end. Humphrey also fails to teach or suggest a lancet holder arranged and configured on the second end of the lancet to move the lancet a penetration distance to penetrate the skin of a patient with the first and second sharpened tips, wherein the penetration distance is less than a length of the

sharpened tips. Humphrey discloses hypodermic needles and lancets that make possible new types of phlebotomy devices and intravenous catheters. (Abstract; Col. 4, lines 16-35). Humphrey's needles allow for deeper penetration. (Col. 3, lines 25-26). The depth of the piercing process can be controlled so that the lancet stopped before "making contact with the supporting base structure. (Col. 8, lines 49-56) Therefore, the combination of Ayres and Humphrey does not teach, suggest or render obvious a penetration distance to penetrate the skin of a patient with the first and second sharpened tips, wherein the penetration distance is less than a length of the sharpened tips as recited in the claims.

Because the combination of Ayres and Humphrey fails to teach, suggest or render obvious as least these elements required by claims 1, 3 and 63, Applicant respectfully submits that claims 1, 3 and 63 and their dependent claims are in condition for allowance, notice of which is requested.

For the reasons set forth above, Applicant traverses the Examiner's rejections and respectfully submits that all pending claims are allowable. Applicant requests the Examiner's early examination of the pending claims in the present application. In the event that the Examiner deems a telephonic discussion would be helpful in advancing the prosecution of the present application, Applicants respectfully request the Examiner to contact Applicants' representative at (248) 244-0163.

Respectfully submitted,

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